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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,173	BURBANK ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 40-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 40-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/25/05, 3/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 48b (see page 15, at line 17). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to because:

In figure 12, "64" should apparently read --74-- as per page 15, at line 24.

In figures 15-16, "12" should apparently read --72--.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and

where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The abstract of the disclosure is objected to because it comprises in excess of 150 words.

Correction is required. See MPEP § 608.01(b).

4. The disclosure is objected to because of the following informalities:

Applicant has not disclosed the current status of the related applications.

Appropriate correction is required.

Claim Objections

5. Claims 40 and 43 are objected to because of the following informalities:

In claim 40, line 1, "form" should read --from--.

In claim 43, at line 3, "radial" should read --radially--.

In claim 51, at line 3, remove "radially" between "said" and "retracted."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 50-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 recites the limitation "the electrosurgical proximal tissue cutting element" in from lines 1-2 of the. There is insufficient antecedent basis for this limitation in the claim. It is unclear as to whether the electrosurgical device comprises a plurality of tissue cutting elements (i.e. a proximal cutting element and a distal cutting element).

Claim 50 recites the limitation "it" in line 2. There is insufficient antecedent basis for this limitation in the claim. One cannot be certain what the pronoun "it" is intended to refer to.

Claim 51 recites the limitation "it" in line 2. There is insufficient antecedent basis for this limitation in the claim. One cannot be certain what the pronoun "it" is intended to refer to.

Claim 54 recites the limitation "the distal tissue cutting element" in line 4. There is insufficient antecedent basis for this limitation in the claim. It is unclear as to whether the electrosurgical device comprises a plurality of tissue cutting elements.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 40-43, and 47-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Kieturakis (US Patent No. 5,794,626).

In regards to claim 1, Kieturakis discloses a biopsy instrument 5 for retrieving body tissue, having a longitudinal axis and comprising: a distal end 45 adapted for entry into a patient's body; and an electrosurgical cutting element 15 disposed on a distal portion of the instrument, which is actuatable between a radially retracted position and a radially extended position to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see figs. 2-3).

In regards to claims 40-43, and 47-53, Kieturakis disclose an instrument assembly for isolating target tissue form an intracorporeal site, comprising:

a. an elongate shaft 40 which has a longitudinal axis and a distal end 45; and

b. an elongated electrosurgical tissue cutting element 15 which is longitudinally disposed on the elongate shaft 40 proximal of the distal end 15 of the shaft 40, which is radially extendable from a retracted position to a radially extended position (see figs. 2-3), which is configured to be rotated at least in part about the longitudinal axis in a radially extended arcuate position while receiving electrical power from a high frequency electrical power source 142 to electrosurgically isolate a desired tissue specimen from

surrounding tissue by defining a peripheral margin about at least part of the tissue specimen (see column 6/lines 13-19);

wherein the electrosurgical cutting element further includes an electrical conductor configured to electrically interconnect the electrosurgical tissue cutting element 15 to high frequency electrical power source 142 (see column 6/lines 44-62);

wherein the electrosurgical cutting element 15 has a proximal end 23 and a distal end 24 and which is configured to move one end closer to the other end to effect radial extension from the retracted position to the radial extended position (see fig. 2);

wherein the electrosurgical cutting element 15 is configured so that the distal end 24 is fixed and the proximal end 23 moves toward the distal end 24 in order to radial extend the electrosurgical cutting element 15;

wherein the electrosurgical cutting element 15 is configured to be manipulated to segment the tissue specimen (see column 3/lines 64-67);

wherein the electrosurgical proximal tissue cutting element 15 is configured to segment the tissue specimen after it has been isolated from the surrounding tissue;

wherein the tissue cutting element 15 is configured to segment the tissue specimen as it is being retracted from said radially extended position to said radially retracted position;

wherein the radially extended position comprises a first radially extended position, and wherein the electrosurgical cutting element 15 is further actuatable to a plurality of additional radially extended positions and rotatable about the longitudinal

axis in each of said radially extended positions to selectively peripherally segment said tissue specimen;

Wherein the instrument assembly 5 further comprises a cannula 10 having a lumen 56 for providing a passageway into the patient's body, the segments of the tissue specimen being removable from the patient's body through the cannula 10 (see fig. 3).

In regards to claim 54, Kieturakis discloses a system 5 for isolating body tissue, comprising:

a. an elongate shaft 40 having a longitudinal axis and a distal end 45;

b. an electrosurgical tissue cutting element 15 disposed on the elongate shaft 40 proximal of the distal tissue cutting element 15 which is radially extendable from a radially retracted position to a radially extended position, relative to the longitudinal axis, having an arcuate shape and being movable in said radially extended position and arcuate shape to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen; and

c. a source 142 of radiofrequency energy which is electrically connected to the electrosurgical tissue cutting element 15 (see figs. 2-3, 5-8; column 6/lines 44-62);

wherein the system 5 further comprises a cannula 10 having a lumen 56 for providing a passageway 56 into the patient's body, the segments of the tissue specimen being removable from the patient's body through the cannula (see fig. 3).

10. Claims 1, 40-46, 49-52, and 54-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Essig et al. (US Patent No. 5,397,320).

In regards to claim 1, Essig et al. disclose a biopsy instrument 10 for retrieving body tissue, having a longitudinal axis and comprising: a distal end adapted for entry into a patient's body; and an electrosurgical cutting element 16 disposed on a distal portion of the instrument 10, which is actuatable between a radially retracted position and a radially extended position to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see column 2/lines 29-37, 54-59).

In regards to claims 40-46, and 49-52, Essig et al. disclose an instrument assembly for isolating target tissue form an intracorporeal site, comprising:

a. an elongate shaft 12 which has a longitudinal axis and a distal end; and

b. an elongated electrosurgical tissue cutting element 16 which is longitudinally disposed on the elongate shaft 12 proximal of the distal end of the shaft 12, which is radially extendable from a retracted position to a radially extended position, which is capable of being rotated at least in part about the longitudinal axis in a radially extended arcuate position while receiving electrical power from a high frequency electrical power source 18 to electrosurgically isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about at least part of the tissue specimen (see fig. 4);

wherein the electrosurgical cutting element 16 further includes an electrical conductor configured to electrically interconnect the electrosurgical tissue cutting element 16 to high frequency electrical power source 18;

wherein the electrosurgical cutting element 16 comprises a multipolar electrode 14;

wherein the instrument assembly 10 further includes a sheath 30, which is axially movable between distal and proximal positions for selectively covering and uncovering the electrosurgical cutting element 16 (see column 4/lines 24-37);

wherein the electrosurgical cutting element 16 is configured to be manipulated to segment the tissue specimen (see column 2/lines 29-37);

wherein the electrosurgical proximal tissue cutting element 14 is configured to segment the tissue specimen after it has been isolated from the surrounding tissue (see fig. 4);

wherein the tissue cutting element 14 is configured to segment the tissue specimen as it is being retracted from said radially extended position to said radially retracted position (see fig. 4);

wherein the radially extended position comprises a first radially extended position, and wherein the electrosurgical cutting element is further actuatable to a plurality of additional radially extended positions and rotatable about the longitudinal axis in each of said radially extended positions to selectively peripherally segment said tissue specimen (see column 4/lines 24-37).

It is noted that partial coverings of the electrosurgical cutting element 16 will result in a plurality of radially extended positions.

In regards to claims 54-56, Essig et al. disclose a system for isolating body tissue, comprising:

a. an elongate shaft 12 having a longitudinal axis and a distal end;

b. an electrosurgical tissue cutting element 16 disposed on the elongate shaft 12 proximal of the distal tissue cutting element 16 which is radially extendable from a radially retracted position to a radially extended position, relative to the longitudinal axis, having an arcuate shape and being movable in said radially extended position and arcuate shape to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see column 2/lines 29-37, 54-59); and

c. a source 18 of radiofrequency energy which is electrically connected to the electrosurgical tissue cutting element 16;

wherein the electrosurgical tissue-cutting element comprises a multipolar electrode 14 (see fig. 1).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,331,166.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 recites "a biopsy instrument for retrieving body tissue" (see line 1 of claim 1 of the patent), "a longitudinal axis" and "a distal end" (see lines 3-4 of claim 1 of the patent), "an electrosurgical tissue cutting element disposed on said distal end of the instrument" (see lines 5-9 of claim 1 of the patent).

It is clear that all the elements of claim 1 of the instant application are to be found in claim 1 of the patent. The difference between claim 1 of the instant application and claim 1 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of claim 1 of the patent is in effect a "species" of the "generic" invention of claim 1 of the instant application. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman,* 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 1of the instant application is anticipated by claim 1 of the patent, it is not patentably distinct from claim 1 of the patent.

13. Claims 40, 44-49, and 51-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,699,206.

In regards to claims 40, 44-49, and 51-53, although the conflicting claims are not identical, they are not patentably distinct from each other because claim 40 recites "an instrument for isolating target tissue from intracorporeal site" (see line 1 of claim 1 of the patent), "an elongate shaft which has a longitudinal axis and a distal end" (see lines 2-3 of claim 1 of the patent), "an elongated electrosurgical tissue cutting element disposed on the elongate shaft proximal of the distal end of the shaft" (see lines 4-9 of claim 1 of

the patent), "a high frequency electrical power source" (see line 17 of claim 1 of the patent).

Similarly claim 44, which is dependent on claim 40, further recites, "the electrosurgical element comprises a monopolar electrode" (see lines 1-3 of claim 9, which depends on claim 8 which depends on claim 1 of the patent).

Similarly claim 45, which is dependent on claim 40, further recites, "the electrosurgical element comprises a bipolar electrode" (see lines 1-3 of claim 10, which depends on claim 8 which depends on claim 1 of the patent).

Similarly claim 46, which is dependent on claim 40, further recites, "a sheath which is axially movable" (see claim 5, which depends on claim 1 of the patent).

Similarly claim 47, which is dependent on claim 40, further recites, "a proximal driver unit" (see line 2 of claim 6, which depends on claim 5, which depends on claim 1 of the patent).

Similarly claim 48, which is dependent on claim 47, which is dependent on claim 40, further recites, "the proximal driver unit further controls axial movement of said shaft" (see lines 1-3 of claim 7, which depends on claim 6 which depends on claim 1 of the patent).

Similarly claim 49, which is dependent on claim 40, further recites, "electrosurgical element is configured to be manipulated to segment the tissue" (see claim 11, which depends on claim 6, which depends on claim 5, which depends on claim 1 of the patent).

Similarly claim 51, which is dependent on claim 49, which is dependent on claim 40, further recites, "the tissue cutting element is configured to segment the tissue specimen" (see claim 12, which depends on claim 11 which depends on claim 6 which depends claim 5 which depends on claim 1 of the patent).

Similarly claim 52, which is dependent on claim 51, which depends on claim 49, which is dependent on claim 40, further recites, "the radially extended position" (see claim 13, which depends on claim 12 which depends on claim 11 which depends on claim 6 which depends claim 5 which depends on claim 1 of the patent).

Similarly claim 53, which is dependent on claim 52, which depends on claim 51, which depends on claim 49, which is dependent on claim 40, further recites, "a passageway into the patient's body" (see claim 14, which depends on claim 13, which depends on claim 12 which depends on claim 11 which depends on claim 6 which depends claim 5 which depends on claim 1 of the patent).

It is clear that all the elements of claim 40 are to be found in claim 1 of the patent. The difference between claim 40 of the application and claim 1 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of the claim 1 of the patent is in effect a "species" of the "generic" invention of claim 40. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman,* 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 40 is anticipated by claim 1 of the patent, it is not patentably distinct from claim 1. Similarly, since claims 44-49, and 51-53, are anticipated by claims 9-10, 5-7, and 11-13,

respectively of the patent, claims 44-49, and 51-53 are not patentably distinct from claims 9-10, 5-7, and 11-13, respectively, of patent.

In regards to claim 54, although the conflicting claims are not identical, they are not patentably distinct from each other because claim 54 recites "a system for isolating body tissue" (see line 1 of claim 1 of the patent), "an elongate shaft which has a longitudinal axis and a distal end" (see lines 2-3 of claim 1 of the patent), "an electrosurgical tissue cutting element disposed on the elongate shaft proximal of the distal end of the shaft" (see lines 4-9 of claim 1 of the patent), "a source of radiofrequency energy" (see line 17 of claim 1 of the patent).

It is clear that all the elements of claim 54 are to be found in claim 1 of the patent. The difference between claim 54 of the application and claim 1 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of the claim 1 of the patent is in effect a "species" of the "generic" invention of claim 40. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman,* 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 54 is anticipated by claim 1 of the patent, it is not patentably distinct from claim 1.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,501,694 to Ressemann et al. discloses an improved expandable removal element for an atherectomy device wherein the expandable removal element is movable between an expanded position and a contracted position. In one embodiment

of the present invention, a drive shaft is operatively connected to the distal end of the expandable removal element for rotating the removal element. A catheter surrounds a portion of the drive shaft. The catheter is shiftable with respect to the drive shaft for moving the material removal element between the expanded position and the contracted position. In another embodiment of the present invention, dual coaxial drive shafts are employed. The inner drive shaft and the outer drive are shiftable with respect to one another for moving the removal element between the expanded position and the contracted position.

US Patent No. 5,549,108 to Edwards et al. discloses a cardiac diagnosis and treatment system comprises a support carrying at least two electrodes. A conductor is associated with the support for selectively directing electrical signals to and from each electrode.

US Patent No. 4,532,924 to Auth et al. discloses a multipolar electrosurgical device is described for use in neurosurgery or through the channel of an endoscope or other precision surgery procedures. The device is formed with an insulative probe body, which, in the described embodiment, is sized to pass through a channel of an endoscope to enable the electrocoagulation of blood vessels such as may be needed in the treatment of a gastrointestinal ulcer. The probe body is provided with electrically separate conductors, which are formed of a plurality of electrodes distributed over the peripheral surface of the probe body.

US Patent No. 5,311,858 to Adair discloses an endoscope, which includes an elongated tube, having a distal end and a proximal end. An elongated basket having a

circular distal end with a central opening therein and a proximal end, which is attached to the periphery of the distal end of the tube is provided. The basket is formed as a plurality of spaced flexible members, which normally bow outwardly between the distal end and the proximal end of the basket.

US Patent No. 5,941,869 to Patterson et al. discloses an apparatus including a catheter system having a stenotic material removal mechanism mounted on a distal portion of an elongated inner catheter. A sensing means, such as one or more sensing electrodes, are positioned on an outer surface of the apparatus. In addition, the apparatus optionally includes control means for diametrically expanding the stenotic material removal mechanism for effective recanalization of the stent. A coaxial outer catheter is provided for aspirating stenotic material, which is removed from within the stent.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT

CHARLES MARMOR
PRIMARY EXAMINER